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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,818	08/22/2001	Jean-Michel Bernardon	016800-451	7237

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/933,818	BERNARDON ET AL.	
	Examiner	Art Unit	
	Shaojia A Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2004 and 26 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,8-17 and 22-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,8-17 and 22-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 29, 2004 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed April 29, 2004, and amendment and response to the Final Office Action (mailed August 26, 2003), filed February 26, 2004 wherein claims 4-7 are cancelled; claims 2-3 and 8-17 have been amended; claims are newly submitted.

Currently, claims 2-3, 8-17, and 22-31 are pending in this application.

Claims 2-3, 8-17, and 22-31 are examined on the merits herein.

Applicant's amendment filed February 23, 2004, canceling all previous claims 1-27. Therefore, all rejections of record stated in the previous Office Action dated August 22, 2003 are withdrawn.

As indicated in the previous Office Action January 31, 2003, the recitation, "regime or regimen" for treating in the instant claims is examined as a method of treating herein.

Objection to the Specification

The incorporation of essential material in the specification by reference to an unclear co-pending application is improper, i.e., in [002] at page 1 "Serial No._____" ??/???,???. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-3, 8-17, and 22-31 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling the instant compounds for treating particular skin disorders such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters, disclosed in the specification (page

6), does not reasonably provide enablement for treating any "disorders of barrier function of human skin".

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a method of treating any "disorders of barrier function of human skin".

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since these claims reads on treating any disorders of barrier function of human skin.

Regarding the *Wands* factor (4) the predictability or unpredictability of the art:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant

case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses any disorders of barrier function of human skin, a great numbers of skin disorders, which are known to be involved various, many possible, and different, separate and independent etiologies, for example, various skin infections due to barrier dysfunction (see for example, the Merck Manual of Diagnosis and Therapy (17th ED) (1999), page 1088-1091, PTO-892), which are known to be involved different, separate and independent etiologies from an epidermal lipid secretion disorders or the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters. Thus, the skilled artisan would view that the treatment of all skin barrier function disorders by administering the same particular compound herein, is highly unpredictable.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects and toxicity generated by administering the particular compound herein for treating any skin disorders of barrier function of human skin.

In regard to these *Wands* factors, (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary:

Moreover, it is noted that the specification provides **no** working examples, i.e., testing results or data demonstrating the treatment of skin disorders of barrier function of human skin.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the broad treatment of any skin diseases recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of treating any skin disorders of barrier function of human skin recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation*, with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17 and 31 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular agents disclosed in the specification (see page 8) in co-administering the particular compound of formula (I) herein employed in methods for treatments herein, does not reasonably

provide enablement for the employment any agents for combating free radicals, or any ion channel blockers in combination with the particular compound of formula herein to be administered for the claimed methods of the particular treatments herein, i.e., particular barrier function such as an epidermal lipid secretion disorders in a patient.

These recitations, "agent for combating free radicals" and " ion channel blocker", are seen to be merely functional language.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to methods of treating a barrier function, and an epidermal lipid secretion disorders.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claim 23 is deemed very broad since the claim reads on any agents for combating free radicals or any ion channel blockers employed in the claimed methods of treatment herein.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants in claim 23, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997). The CAFC clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405(emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphases added).

In the instant case, "agent for combating free radicals" and " ion channel blocker" recited in the instant claim are purely functional distinction. Hence, these functional recitations read on any compounds that might have the recited functions. Moreover, the specification does not provide those particular compounds for each kind of functional compounds for the claimed method of treatment herein.

Thus, Applicants functional language at the points of novelty in the claim fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph, since it fails to provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)).

The predictability or unpredictability: the instant claimed invention is highly *unpredictable* as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, except those particular compounds of formula disclosed in the specification, as discussed above in *University of California v. Eli Lilly and Co.* Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the claimed method of treatment herein.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects for treatment of particular skin diseases such as roascea, a skin pigmentation disorder, a seborrhoeic function disorder, a barrier function, and an epidermal lipid secretion disorders, side effects, and especially serious toxicity that may be generated by drug-drug interactions when and/or after administering to a host (e.g., a human), the *combination* of the instant compound of formula (I) and any compounds represented by "agent for combating free radicals" or " ion channel blockers". See text book "Goodman & Gilman's The Pharmacological Basis of Therapeutics" regarding

possible drug-drug interactions (9th ed, 1996) page 51 in particular. This book teaches that "The frequency of significant beneficial or adverse drug interactions is unknown" (see the bottom of the left column of page 51) and that "Recognition of beneficial effects and recognition of and prevention of adverse drug interactions require a thorough knowledge of the intended and possible effects of drugs that are prescribed" and that "The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences" (see the right column of page 51) (emphases added).

In the instant case, in the absence of fully recognizing the identity of the members genus herein except those particular compounds of formula in the specification, one of skill in the art would not be able to fully predict the possible treatments herein and possible adverse effects occurring with many compounds having claimed functional properties and their combinations to be administered to a host in the claimed method herein. Thus, the teachings of the "Goodman & Gilman's" book clearly support that the instant claimed invention is highly unpredictable.

The presence or absence of working examples and the quantity of experimentation necessary:

It is noted that the specification provides **no** working examples, i.e., testing results or data demonstrating that the instant compound of formula (I) in co-administering the particular agent for combating free radicals or particular ion channel

blocker to be administered to a host, i.e., an animal or a human, for the instant methods of treatments.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation* to test all compounds encompassed in the instant claims and their combinations to be administered to a host employed in the claimed methods of the particular treatments herein, with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3, 8-17, and 22-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation " disorders of the barrier function of human skin " renders claims 2-3, 8-17, and 22-31 indefinite. As noted above, during patent examination, claims are given their broadest reasonable interpretation. It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim, However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) for example.

Thus, one of ordinary skill in the art could not ascertain and interpret the metes and bounds as to what disorders of the barrier function of human skin would be. Therefore, the scope of the claims is indefinite as to "a barrier function of the skin disorder" encompassed thereby.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-3, 8-17, and 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernardon (5,763,487, of record).

Bernardon discloses that the active instant compounds of formula (I) including the particular elected compound (the chemical name disclosed at col.3 lines 50-53) are useful in methods of treating dermatological, and skin and hair conditions/disorders broadly such as dermal or epidermal proliferations, a keratinization disorder, and skin aging photoinduced or chronological. See abstract, col.1-2, col.3 lines 50-53, Example 20 at col.16 and claims 12-25. Bernardon also discloses the employment of retinoids, particular vitamin D compounds, corticosteroid, particular α–hydroxy or α–keto acids, and ion channel blockers in the combination with the instant compounds in methods therein (see col.6 lines 67, col7 lines 52-57). Bernardon further discloses that the administered route is topical, enteral, parenteral, or ocular (see col.7 lines 9-11 and 23-33)).

Note that Bernardon discloses the effective amounts of the compound herein in the range of daily dose of about 0.01 to 100 mg/kg of body weight (see col. 7 lines 19-20 and claim 17), which are within or overlapping with the effective amounts, daily dose of about 0.001 to 100 mg/kg of body weight, indicated in Applicant's specification (see page 6, [0029] of the specification).

Bernardon does not expressly disclose a method for treating particular skin disorders, the disorders of the barrier function of human skin such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born

before 33 weeks of age, lip fissures, chapped lips, or blisters by administering the particular compound of Bernardon.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular compound of Bernardon in a method for treating particular skin disorders, the disorders of the barrier function of human skin such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular compound of Bernardon in a method for treating particular skin disorders, the disorders of the barrier function of human skin such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters, because the compound of the prior art is known to be useful in treating dermatological, and skin and hair conditions/disorders such as dermal or epidermal proliferations, a keratinization disorder, and skin aging photoinduced or chronological broadly according to Bernardon. Thus, the dermatological, and skin and hair conditions/disorders taught by Bernardon would encompass the disorders of the barrier function of human skin such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters.

Therefore, the patient population in Bernardon is deemed to encompass the patient herein suffering from the disorders herein.

Therefore, one of ordinary skill in the art would have reasonably expected that the particular compound of Bernardon would have beneficial therapeutic effects and usefulness in methods for treating particular skin disorders such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters by administering the same effective amounts of the same compound of Bernardon.

Applicant's remarks filed February 26, 2004 with respect to the rejection made under 35 U.S.C. 102(b) of record in the previous Office Action August 26, 2003 have been fully considered but are moot in view of the new ground(s) of rejection above.

Additionally, Applicant's remarks with respect to the obviousness over the same prior art have been considered but not found persuasive. These remarks are believed to be adequately addressed by the obvious rejection presented above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-3, 8-17, and 22-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-17 of U.S. Patent No. 5,763,487 (Bernardon).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method of treating dermatological disorder comprising administering the same particular compound of formula (I), in the same effect amount.

The claims of the instant application is drawn to a method of treating the disorders of the barrier function of human skin such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters.

As discussed above, the claimed method herein is seen to be obvious over the claims in the patent.

Thus, the instant claims 2-3, 8-17, and 22-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-17 of U.S. Patent No. 5,763,487.

Claims 2-3, 8-17, and 22-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23, 26, 28, and 35-36 of U.S. Patent No. 6,156,750.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method of treating dermatological disorder, epidermal and/or dermal atrophy, a sebaceous function disorder comprising administering the same particular compound of formula (I), in the same effect amount.

The claims of the instant application is drawn to a method of treating the disorders of the barrier function of human skin such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters.

Based on the same rationale as the obvious rejection under 103(a) set forth above, the claimed method herein is seen to be obvious over the claims in the patent.

Thus, the instant claims 2-3, 8-17, and 22-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23, 26, 28, and 35-36 of U.S. Patent No. 6,156,750.

Claims 2-3, 8-17, and 22-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-29 and 32-41 of copending Application No. 10/224,449.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to the same method of treatment for the barrier function of human skin such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters, comprising administering the same

since the structural formula (I) in claim 28 of the copending application overlaps and/or read on the instant structural formula (I) in claims 2 and 22.

Thus, the copending Application No. 10/224,449 and the instant claims are seen to substantially overlap.

Thus, the instant claims are seen to be obvious over the all claims of copending Application No. 10/224,449.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
June 25, 2004